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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/676,568

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Trudee Klautky

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EXAMINER

ALEXANDER, LYLE

ART UNIT

PAPER NUMBER

1797

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/676,568	<b>Applicant(s)</b> KLAUTKY ET AL.	
	<b>Examiner</b> Lyle A. Alexander	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,5-7,10,11,14,15,21-24,28,29 and 39-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,5-7,10,11,14,15,21-24,28,29 and 39-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 41 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 41 is not complete. What happens if the sample has an adequate concentration of cells?

***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,5-7,10-11,14-15,22, 24,28-29 and 39-41 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Weid et al. (USP 4,129,381).

Weid et al. as characterized by Applicants 6/9/09 IDS is characterized as teaching all of the elements of the instant invention. See this characterization for the teachings of Weid et al.

Additionally, Weid et al. teach an automated method and apparatus for preparing a suspension of cells for cytological analysis. The sample is adjusted to contain the appropriate number of cells based upon a coulter counter which has been read on the "optical interrogating". Weid et al. teach if the sample has sufficient cellular concentrations it is OK for analysis. The Office has read this on the claimed "positive designator." If the sample does not contain sufficient cells, then more cells are added.

The Office has read this on the claimed "manipulation designator" and " ... a manipulation to render the solution containing the initial sample satisfactory for slide preparation."

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,5-7,10-11,14-15, 21-24, 28-29 and 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Isenstein et al. (US 2004/0253144).

See the appropriate paragraph of the 2/9/09 Office action for the teachings of Isenstein et al.

Isenstein et al. teach analysis of cervical/vaginal cells which has been read on the claimed "endocervical cells."

Additionally, Isenstein et al. teaches in paragraph[59] and figure 6 each slide is initially examined for the proper number of cells. If the cells on the slide fall within the desired range of 10 to 30 ASCUS+, the slide is accepted as a sample candidate. The acceptance of the slide has been read on the claimed "attaching a positive designator" and these steps have been read on the claimed step "d) determining , ... sample has adequate concentration of cellular material ...". Paragraph[60] teaches if the sample is outside of the 10-30 ASCUS+ cell range the sample is either discarded or diluted respectively (see figure 6). This has been read on the claimed "manipulation designator" and these steps have been read on the claimed "g) attaching a manipulation

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designator ... a manipulation to render the solution containing the initial sample satisfactory for preparing a specimen slide." The claims differs from Isenstein et al. in the limitation "e) obtaining additional sample cytological sample from the patient to the added to the solution if the solution containing the initial sample does not have adequate concentration of cellular material;". Rather, Isenstein et al. only teach further dilution of a sample with too high a concentration of cells and not addition of more cells to a sample with too few cells.

It is well settled to use known techniques to improve similar methods in the same way. Isenstein et al. teaches if a sample has too high a concentration of cell, it can be diluted and a subjected to further processing. Isenstein et al. teach the sample with too low of a cellular concentration are discarded. It is desirable to use a minimal amount of sample. It would be desirable to avoid discarding the samples with too low cell concentration. It would be desirable to adjusting the cellular concentration of the sample by the addition of cells because it is known to adjust the cellular concentration in a sample for optimal analysis (e.g. Isenstein et al. teach adjusting the concentration of cells with too high of a concentration). It would have been within the skill of the art to modify Isenstein et al. and add more cells to a sample with too low a concentration to gain the advantages of using the minimal amount of sample for analysis.

Isenstein et al. are silent to placing a "marking on the vessel" to indicate information or the status of the sample.

The basic technique of putting indicia on data which then enabled standard sorting, searching, and reporting yielded no more than the predictable outcome which

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one of ordinary skill would have expected to achieve with this common tool of the trade and was therefore an obvious expedient. The Court held that “[t]he gap between the prior art and respondent’s system is simply not so great as to render the system nonobvious to one reasonably skilled in the art.”*Id.* at 230, 189 USPQ at 261.

It would have been within the skill of the art to modify Isenstein et al. and place indicia on the sample container to enable sorting and searching as an obvious expedient.

Claim 21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weid et al.

See Weid et al. *supra*.

Weid et al. are silent to placing a “marking on the vessel” to indicate information or the status of the sample.

The basic technique of putting indicia on data which then enabled standard sorting, searching, and reporting yielded no more than the predictable outcome which one of ordinary skill would have expected to achieve with this common tool of the trade and was therefore an obvious expedient. The Court held that “[t]he gap between the prior art and respondent’s system is simply not so great as to render the system nonobvious to one reasonably skilled in the art.”*Id.* at 230, 189 USPQ at 261.

It would have been within the skill of the art to modify Weid et al. and place indicia on the sample container to enable sorting and searching as an obvious expedient.

### ***Response to Arguments***

Applicant's arguments filed 6/9/09 have been fully considered but they are not persuasive.

Applicant's 6/9/09 amendments have obviated the 35 USC 112 second paragraph rejections that were made in the 2/9/09 final rejection.

In light of the 6/9/09 amendments and remarks, the rejection over Zahniser et al. and Zahniser et al. in view of Zweig have been vacated.

Applicants state Isenstein et al. fails to teach any of the claimed method steps. The Office has particularly pointed out above how figure 6 of Isenstein et al. reads on the instant claims. The Office maintains the rejections over Isenstein et al. are proper.

Applicants state Isenstein et al. fails to teach the claimed attachment of a positive designator and manipulation designator. Isenstein et al. clearly teaches in figure 6 analysis of a sample for the proper cell concentration. If the proper cell concentration is present, the sample is identified as such and is further processed. If the cell concentration is too high or low, the sample is identified as such and appropriately processed. These two different identifications of the cells indicate the cells are either satisfactory for further analysis or not satisfactory for the further analysis and is indistinguishable from the instant claims.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The 6/9/09 IDS cited by Applicants' provided comments made by

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the Australian Patent Office concerning USP 5,266,495; 4,129,381; 3,872,805. The Office has considered remarks made by the Australian Patent Office and has also considered the above USP's. To be complete, the Office is making these three USP's of record and making their interpretations of references not cited in an art rejection below.

Lapidus (USP 5,266,495) teaches a method and apparatus for supplying the appropriate volume of cells based upon filtration pressures. The Office has not cited Lapidus against the instant claims because it lacks the claimed "optical interrogation" to determine the number of cells and the claimed steps of applying a manipulation designator and further manipulation that adds cells.

Mansfield et al. (USP 3,827,805) teach a system for adding a predetermined amount of cells to a centrifuge. This reference lacks a teaching of the "endocervical cells" of dependent claim 14 and is not as relevant as the art cited in the 35 USC 102 and 103 rejections.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lyle A Alexander  
Primary Examiner  
Art Unit 1797

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